K071916

B. 510(k) SUMMARY (as required by 21 CFR 807.92) JUN - 2 2008

Metha® Hip System
July 10, 2007

COMPANY:	Aesculap Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Kathy A. Racosky 610-984-5092 (phone) 610-791-6882 (fax)
TRADE NAME:	Metha®
COMMON NAME:	Metha® Hip System
CLASSIFICATION NAME:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
REGULATION NUMBER:	888.3360, 888.3353, 888.3390
PRODUCT CODE:	LWJ, MEH, KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the Metha® Hip System is substantially equivalent to:

- Excia Total Hip System (K042344)
- Excia Total Hip System with µ-CaP® (K060437)
- Pro-Femur (K012091)
- MAYO® Conservative Hip Prosthesis (K030733)
- Apex Modular HA Hip Stem (K043123)

DEVICE DESCRIPTION

The Metha® Hip System is a modular system which consists of two components; the stem and the neck. Each component is available in various sizes. The conical shaped stem is manufactured from titanium alloy. The proximal area of the femoral stem is plasma sprayed (Plasmapore®) with a secondary coating of Calcium Phosphate (µ-CaP®). This stem is designed for cementless use only.

The modular cone adapter option allows the user to choose a combination of stem, neck, and head component to appropriately fit the individual patient. The modular cone adapter is manufactured from CoCr29MO.

INDICATIONS FOR USE

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems Metha® Hip System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the:

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance for Femoral Stem Prostheses",
- "Draft Guidance for Calcium Phosphate (Ca-P) Coating" was completed where applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2008

Aesculap Implant Systems, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K071916
Trade/Device Name: Metha® Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LWJ, KWY
Dated: April 30, 2008
Received: May 1, 2008

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K071916

Device Name: Metha® Hip System

Indications for Use:

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

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- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

Neil R Ogden for mkm

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative,

and Neurological Devices

510(k) Number K071916